

CARELLA, BYRNE, CECCHI, OLSTEIN,  
BRODY & AGNELLO, P.C.  
JAMES E. CECCHI  
5 Becker Farm Road  
Roseland, NJ 07068  
Telephone: 973/994-1700  
973/994-1744 (fax)

Attorneys for Plaintiff

[Additional counsel appear on signature page.]

UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY

CITY OF WARREN GENERAL	)	No.
EMPLOYEES' RETIREMENT	)	
SYSTEM, Individually and on Behalf	)	<u>CLASS ACTION</u>
of All Others Similarly Situated,	)	
	)	COMPLAINT FOR VIOLATIONS OF
Plaintiff,	)	THE FEDERAL SECURITIES LAWS
	)	
vs.	)	
	)	
CELGENE CORPORATION, MARK	)	
J. ALLES, PETER N. KELLOGG,	)	
SCOTT A. SMITH, NADIM AHMED	)	
and TERRIE CURRAN,	)	
	)	
Defendants.	)	
_____	)	<u>DEMAND FOR JURY TRIAL</u>

Plaintiff City of Warren General Employees' Retirement System ("plaintiff"), individually and on behalf of all others similarly situated, by plaintiff's undersigned attorneys, for plaintiff's complaint against defendants, alleges the following based upon personal knowledge as to plaintiff and plaintiff's own acts and upon information and belief as to all other matters based on the investigation conducted by and through plaintiff's attorneys, which included, among other things, a review of U.S. Securities and Exchange Commission ("SEC") filings by Celgene Corporation ("Celgene" or the "Company"), Company press releases and earning calls, and analyst and media reports about the Company. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

### **SUMMARY OF THE ACTION**

1. This is a federal securities class action on behalf of all persons or entities who purchased Celgene common stock between September 12, 2016 and February 27, 2018, inclusive (the "Class Period"), seeking remedies under the Securities Exchange Act of 1934 (the "1934 Act"). These claims are asserted against Celgene and certain of its officers and/or directors who made materially false or misleading statements during the Class Period.

2. Celgene is a biotechnology company that specializes in the discovery, development and commercialization of therapies for the treatment of cancer and

inflammatory diseases. Its most successful drug is Revlimid, a drug for the treatment of multiple myeloma (a type of plasma cell cancer). The majority of Celgene's net sales derive from Revlimid, and the drug accounted for more than 60% of Celgene's total net product sales for the year ended December 31, 2016. The Company has also relied on dramatic increases in the price of Revlimid to drive revenue growth in recent years. Since 2010, the price of treatment with Revlimid has tripled to more than \$20,000 per month.

3. Revlimid will lose its patent exclusivity in the coming years, at which point cheaper generics will be able to enter the market. As a result, before and during the Class Period, it was important to investors that the Company develop and successfully commercialize new drugs to diversify and ultimately replace its reliance on revenues from Revlimid sales. Three of the most promising drugs in Celgene's product pipeline to replace Revlimid were: (i) GED-0301, a late-stage developmental treatment for Crohn's disease; (ii) Otezla, a commercial-stage treatment for psoriasis approved by the FDA in 2014; and (iii) Ozanimod, a developmental treatment for relapsing multiple sclerosis and ulcerative colitis.

4. In April 2014, Celgene acquired GED-0301 from Irish-based pharmaceutical startup Nogra Pharma Limited ("Nogra") for \$710 million. At the time, Celgene hailed the drug as a "potentially transformative therapy" that had demonstrated "striking clinical activity in a phase II trial." According to Celgene,

over half of the patients in the study who took higher doses of GED-0301 achieved clinical remission as compared to a placebo or lower doses. The Company stated that it would begin registration for a phase III trial by the end of 2014.

5. Celgene and its top executives went to great lengths to dispel investors' concerns regarding the viability of GE-0301. Following the drug's acquisition, they began touting GED-0301 as "a multibillion-dollar asset" and, together with Otezla and Ozanimod, as an eventual "replacement" for the Company's Revlimid revenues. As an expression of the confidence management purportedly had in GED-0301, Otezla, Ozanimod and Celgene's other pipeline products, in January 2015 the Company unveiled a five-year strategic plan. The Company projected \$21 billion of net product sales by 2020, or nearly triple the Company's total net product sales for fiscal 2014, which included hundreds of millions of dollars of sales from GED-0301 and an expansion in Otezla sales.

6. At the start of the Class Period, on September 12, 2016, the Company released topline data from an interim endoscopy trial for GED-0301, known as "CD-001." The Company hailed the CD-001 results as demonstrating "both endoscopic improvements and clinically meaningful responses and remission at an early timepoint in this study." By enrolling more severe Crohn's disease patients across a wider variety of test sites, the study was designed to address and dispel investor concerns related to phase II trial results. As Celgene's Global Head of Medical Affairs stated at

the time, “*With the interim results from CD-001, we now feel more confident most of the questions have been addressed.*” In the following weeks, the Company continued to receive interim trial data about the efficacy of GED-0301 and to analyze these data, as CD-001 entered a 52-week observational phase after the treatment phase and the Company continued to analyze data from the treatment phase.

7. Celgene had failed to use a placebo control arm in the CD-001 trial, forcing investors to rely on management’s positive characterizations of the drug’s potential. When pressed to defend the lack of a placebo control arm during an analyst call discussing the results, a Company representative claimed that any placebo would have shown “nearly zero” endoscopic remission given the severity of the baseline patient population. In truth, Celgene had designed a faulty interim endoscopy trial in order to dispel investor concerns about its phase II trial, while misrepresenting the import of the results. As Celgene and its top management knew, or recklessly disregarded, but failed to disclose, GED-0301 had not shown meaningful or sustained efficacy through the interim endoscopy trial, and the phase III trial had a materially greater likelihood of failure than publicly disclosed.

8. Over the next year, top Company executives participated in more than a dozen analyst calls, industry conferences and investor meetings in which they claimed that GED-0301 continued to show transformative promise, that the Company’s 2020 guidance would be met or exceeded, and that Celgene would be able to develop the

revenue streams necessary to replace Revlimid and continue the Company's growth. For example, during a January 9, 2017 analyst conference, Celgene's Chief Executive Officer ("CEO") Mark J. Alles touted GED-0301, Ozanimod and Otezla as "an opportunity to, *literally, change the entire landscape* of how these diseases are treated over the next year to 10 years" and help "create *a multi-billion-dollar* add on to our current product portfolio." Similarly, on September 14, 2017, Chief Financial Officer ("CFO") Peter N. Kellogg told investors that Celgene had a "tremendously powerful and rich pipeline," with GED-0301 as a key component that "*will drive our business . . . throughout the entire next decade.*" On September 26, 2017 – with only four days left in Celgene's third fiscal quarter – the Company's President of Hematology & Oncology, Nadim Ahmed, stated that Celgene had great "*visibility*" from recent trial data indicating that GED-0301 would be a potential "*blockbuster*," that Otezla's "ex U.S. sales" were growing "*at a greater than 100% clip*," and that, as a result, the Company was "*very, very confident about 2020* in terms of meeting or exceeding our expectations."

9. Less than one month after the last of these statements to investors, on October 19, 2017, the Company shocked investors when it revealed that it would be abandoning its long-touted drug GED-0301 and discontinuing ongoing trials and would record a *\$1.6 billion impairment charge* (with certain offsets) as a result of the drug's failure. The move followed a futility analysis by an independent Data

Monitoring Committee that had determined the drug was ineffective, notwithstanding management's earlier contentions to the contrary. On this news, the price of Celgene stock fell \$14.63 per share to close at \$121.33 per share on October 20, 2017, a one-day decline of nearly 11%.

10. Then, on October 26, 2017, Celgene released its third quarter 2017 results. The Company once again surprised investors by revealing that certain key drugs had missed expectations for the quarter. Most notably, sales for Otezla – which Celgene representatives had just recently claimed were “going very, very well” – had in fact slowed to only 2% U.S. growth, compared to 41% year-over-year U.S. growth the prior quarter. The Company also posted only an 87% increase in international sales, far below the “greater than 100% clip” touted by Company representatives at the end of the quarter. Worse still, Celgene revised downward its 2020 guidance as a result of the poor results and the loss of projected GED-0301 revenues. While guidance for total product sales was lowered from \$21 billion to a range of \$19 billion to \$20 billion, management *raised* projections for Revlimid and its existing hematology products, with these drugs' proportion of overall sales increasing from 62% in the original guidance to up to 77% of total projected product sales in the revised guidance. Consequently, the Company revealed that it was much more dependent on Revlimid sales for its future success than it had previously disclosed.

On this news, the price of Celgene stock plummeted another \$19.57 per share to close at \$99.99 per share on October 26, 2017, a one-day decline of over 16%.

11. In the wake of these shocking disclosures, defendants sought to reassure investors about the Company's product pipeline and ability to replace Revlimid revenues by pointing to the sales potential of Ozanimod. For example, on the October 26, 2017 conference call to discuss the Company's third quarter 2017 results, defendant Alles stated that the Company would "immediate[ly] shift from GED-0301 to ozanimod in Crohn's disease," and cited this treatment as "a great example of the pipeline optionality and opportunity we have built and continue to build into our research." In subsequent months, defendants described Ozanimod as the "platform molecule" of the Company, with expected sales revenue in the billions, and touted Celgene's submission of its new drug application ("NDA") for Ozanimod to the FDA at the end of 2017 as an indication that the Company was on track to achieve these sales goals.

12. On February 27, 2018, Celgene once again stunned investors when it revealed that the FDA had issued a Refusal to File letter for the Company's developmental multiple sclerosis treatment, Ozanimod. The FDA cited both the nonclinical and clinical pharmacology sections in the NDA as insufficient to permit a complete review. Market reaction was swift and severe, with one commentator calling

Celgene's failure "hard to accept as a reality; *it's almost unheard of for a major company.*"

13. On this news, the price of Celgene stock dropped 9%, or \$8.66 per share, to close at \$87.12 per share on February 28, 2018.

14. As a result of defendants' wrongful acts and omissions, plaintiff and the Class (as defined below) purchased Celgene common stock at artificially inflated prices. However, after the above revelations entered the market, the price of the Company's stock plummeted more than 40% below its Class Period high, causing economic harm and damages to plaintiff and the Class and billions of dollars in lost market capitalization for the Company.

### **JURISDICTION AND VENUE**

15. The claims asserted herein arise under and pursuant to §§ 10(b) and 20(a) of the 1934 Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5, 17 C.F.R. § 240.10b-5, promulgated thereunder by the SEC.

16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and § 27 of the 1934 Act.

17. Venue is proper in this District pursuant to § 27 of the 1934 Act and 28 U.S.C. § 1391(b). The Company is headquartered in this District and many of the acts charged herein, including the preparation and dissemination of materially false and misleading information, occurred in substantial part in this District.

18. In connection with the acts alleged in this complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications and the facilities of the NASDAQ Global Select Market (“NASDAQ”), a national securities exchange.

### **THE PARTIES**

19. Plaintiff City of Warren General Employees’ Retirement System, as set forth in the accompanying certification, purchased Celgene common stock during the Class Period and was damaged thereby.

20. Defendant Celgene is a biotechnology company headquartered in Summit, New Jersey.

21. Defendant Mark J. Alles (“Alles”) has been the CEO of Celgene since March 2016 and its Chairman of the Board since February 6, 2018. He previously served as the Company’s President and Chief Operating Officer (“COO”).

22. Defendant Peter N. Kellogg (“Kellogg”) has been the CFO of Celgene since August 2014.

23. Defendant Scott A. Smith (“Smith”) has been the President and COO of Celgene since April 2017. He previously served as the President of Celgene’s Global Inflammation and Immunology (“I&I”) reporting segment.

24. Defendant Nadim Ahmed (“Ahmed”) has been the President of Celgene’s Hematology & Oncology Franchise since August 2017. He previously served as the

President of Celgene's Worldwide Markets for the Hematology & Oncology Franchise.

25. Defendant Terrie Curran ("Curran") has been the President of Celgene's Global I&I reporting segment since April 1, 2017. She previously served as the Head of WorldWide Markets for I&I.

26. The defendants referenced above in ¶¶21-25 are collectively referred to herein as the "Individual Defendants." The Individual Defendants made, or caused to be made, false and misleading statements that artificially inflated the price of Celgene common stock during the Class Period.

27. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Celgene's quarterly reports, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. They were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions with the Company and their access to material non-public information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive

representations being made were then materially false and misleading. The Individual Defendants are liable for the false and misleading statements pleaded herein.

### **FRAUDULENT SCHEME AND COURSE OF BUSINESS**

28. Defendants are liable for: (i) making false statements; or (ii) failing to disclose adverse facts known to them about Celgene. Defendants' fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Celgene common stock was a success, as it: (i) deceived the investing public regarding Celgene's prospects and business; (ii) artificially inflated the prices of Celgene common stock; and (iii) caused plaintiff and other members of the Class to purchase Celgene common stock at artificially inflated prices.

### **FACTUAL BACKGROUND**

29. Celgene is a large biotechnology company based in Summit, New Jersey. It specializes in treatments for cancer and inflammatory diseases through next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation.

30. The Company has historically generated the majority of its revenues from the sale of Revlimid, which is currently approved to treat multiple myeloma, or plasma cancer. Revlimid is a derivative of thalidomide (which Celgene also sells under the trade name Thalomid). For years, the Company had sustained its growth by increasing sales for Revlimid, including through controversial sales practices and

price increases. For example, the price of treatment with Revlimid has tripled since 2010 to approximately \$20,000 a month. In addition, in July 2017, Celgene agreed to pay \$280 million to settle a whistleblower lawsuit that claimed the Company had defrauded the government and knowingly pushed Revlimid and Thalomid for unapproved off-label uses. The whistleblower, a former sales representative for the Company, alleged that Celgene had paid kickbacks to doctors in order to induce them to use these risky and powerful drugs on cancer patients in a manner “tantamount to ongoing human experimentation.”

31. Adding to the unsustainable nature of Celgene’s Revlimid revenue growth, the drug will lose patent exclusivity in the coming years. Revlimid will go off-patent in the European Union in 2024 and in the United States in 2027. However, the Company has been embroiled in litigation with competitors who would like to sell generic versions of the drug earlier. In 2015, Celgene settled with one of its competitors, Natco Pharma Ltd., and agreed to allow it to sell a limited quantity of Revlimid generics beginning in 2022. Once Celgene’s patent for Revlimid expires, cheaper generic versions of the drug will be able to enter the marketing, driving down the cost of Revlimid and, consequently, Celgene’s revenues and expected future cash flows.

32. As a result of the expected long-term decline in Revlimid revenues, before and during the Class Period it was critical to investors that the Company

develop and successfully commercialize new treatments to continue its revenue growth. Three pipeline drugs were particularly critical to this strategic plan: GED-0301, Otezla and Ozanimod. All three treatments are within Celgene's I&I reporting segment.

33. GED-0301, an oral antisense oligonucleotide compound, is a developmental treatment for Crohn's disease. In April 2014, Celgene purchased GED-0301 from Nogra, an Irish pharmaceutical company, for \$710 million following a phase II trial. At the time, defendant Smith hailed the drug as "a potentially transformative therapy" that demonstrated "striking clinical activity in a phase II trial for Crohn's disease." Later, after the full trial results were published in March 2015, Celgene and Company representatives continued to tout the drug's potential. For example, following the publication and presentation of the trial's primary findings, defendant Smith stated that "[t]he analysis . . . suggests that patients with more severe Crohn's disease or a longer duration of disease were able to achieve clinical response or clinical remission with the 160 mg dose of GED-0301."

34. While most analysts accepted the positive views of management, Celgene went to great lengths to dispel investors' concerns about the viability of GED-0301 as it launched a phase III trial, known as "CD-002." In the months following the drug's acquisition, Celgene representatives began touting GED-0301 as "a multibillion-dollar asset" and, together with Otezla (which was approved to treat psoriasis in 2014) and

Ozanimod (a multiple sclerosis drug under development), as a “replacement” for Revlimid.

35. In January 2015, the Company unveiled a five-year strategic plan to express management’s “confidence” in Celgene’s continued revenue growth. As part of this guidance, the Company projected \$21 billion of net product sales by 2020, or nearly triple the Company’s total net product sales for fiscal 2014, which included hundreds of millions of dollars of sales from GED-0301 and an expansion in sales of Otezla. Sales of I&I, which included GED-0301, Ozanimod and Otezla, were projected to grow to \$3 billion. On a January 29, 2015 analyst conference call discussing the new guidance and the Company’s recent financial results, Celgene’s then-President of Global Hematology & Oncology, Jackie Fouse, stated: “The results of these [new indication] efforts will drive not only our short-term growth trajectory, but they also position us extremely well to sustain that growth, one reason we feel highly confident in our vision out to 2020.” These statements and others like them remained alive in the market and uncorrected at the start of the Class Period.

**DEFENDANTS’ MATERIALLY FALSE AND/OR MISLEADING  
STATEMENTS ISSUED DURING THE CLASS PERIOD**

36. The Class Period begins on September 12, 2016. On that date, the Company issued a press release entitled “Celgene Announces Interim Topline Data from Trial of Investigational Oral GED-0301 in Patients with Active Crohn’s Disease.” The release discussed the topline results from an interim endoscopy trial,

CD-001, that had enrolled 63 patients with moderate to severe Crohn's disease. The release stated that the “[d]ata show *endoscopic improvement and clinical response and remission at week 12.*” The release continued in pertinent part:

Celgene Corporation today announced interim topline data from a randomized, double-blind, multicenter, exploratory phase 1b study evaluating the effects of oral GED-0301 (mongersen) on both endoscopic and clinical outcomes in patients with active Crohn's disease.

The trial, CD-001, is an ongoing study evaluating three different treatment regimens of GED-0301 in a 12-week treatment phase, followed by an observation phase up to 52 weeks (off treatment). The primary objective of the study is to explore the effect of GED-0301 on endoscopic outcomes. The trial enrolled a total of 63 patients across multiple countries.

The study was designed to further enhance the understanding of GED-0301 activity in a difficult-to-treat, moderate-to-severe patient population. This population was more diverse than prior GED-0301 studies and included patients with endoscopically confirmed mucosal damage at entry and those who had previous surgeries. The study also included both biologic exposed and biologic naïve patients as well as patients with a diagnosis of Ileitis, Ileocolitis or colitis.

Topline data from CD-001 show that in a proportion of patients treated with oral GED-0301 there was endoscopic improvement (defined as a 25 percent improvement from baseline) and clinical response and remission across all treatment groups at week 12. Findings to date reveal no new safety signals and tolerability is consistent with earlier studies.

“Given the high unmet need in Crohn's disease, *we are pleased that oral GED-0301 showed both endoscopic improvements and clinically meaningful responses and remission at an early timepoint in this study,*” said Scott Smith, President of Celgene Inflammation and Immunology. “*These data are particularly encouraging for several reasons, including the difficult-to-treat patient population evaluated in the trial.*”

“At this early 12-week timepoint, we’re looking at the proportion of patients who had a 25 percent or greater endoscopic improvement, suggesting mucosal healing is underway in these patients,” said Dr. William Sandborn, M.D., Professor of Medicine and Chief, Division of Gastroenterology and Director, University of California San Diego Inflammatory Bowel Disease Center. ***“These data support the notion that GED-0301, a potential first-in-class oral antisense therapy, may target an underlying cause of Crohn’s disease, rather than simply improving symptoms.”***

Full data from the 12-week timepoint have been submitted for presentation at an upcoming scientific meeting later this year. The CD-001 study is ongoing until all patients complete the observation phase. Data from the observation portion of the trial are expected in 2017. The Phase III registration program is ongoing.

### **About CD-001**

CD-001 is a phase 1b randomized, double-blind, multicenter, exploratory study evaluating the effects of oral GED-0301 on endoscopic and clinical outcomes in patients with active Crohn’s disease. A total of 63 patients were randomized in a 1:1:1 ratio to receive one of three treatment regimens in a 12-week treatment phase: GED-0301 160 mg once daily for 12 weeks; GED-0301 160 mg once daily for eight weeks followed by four weeks of placebo; or GED-0301 160 mg once daily for four weeks followed by eight weeks of placebo. This treatment phase was followed by an off-treatment observation phase for up to 52 weeks. Eligible patients can also enter an extension phase (on treatment) for an additional 24 weeks.

37. By enrolling patients with more severe Crohn’s disease across a wider variety of test sites, the study was designed to address and dispel investor concerns related to the earlier phase II trial results.

38. While some analysts questioned the study’s lack of a placebo control arm, Celgene pushed back against these concerns. For example, speaking at an analyst conference on September 12, 2016, defendant Smith dismissed any issues with

the study's design because of the more extensive disease at baseline of the patients in the study and stressed that the results were meaningful and indicative of the drug's efficacy and supported the Company's design of the phase III trial, CD-002:

So we kept a very topline, *we were very, very encouraged by what we saw in the particular study. We saw endoscopic improvements, clinical responses and clinical remissions across all three groups.*

\* \* \*

*I would expect the placebo rate in this particular population, this study from an endoscopic perspective to be very, very low.* This confirms significant extensive disease at baseline, you wouldn't expect the placebo patients to be getting better, you'd probably expect the majority of them [to be] getting worse over that 12-week period, it would be unlikely that you would get many responses. *So you would expect a low placebo rate* given what we've done here, so what you'd want is to be able to feel good that you could separate from placebo and show statistically significant effects in our large powered study than you would achieve that end point.

And having looked at all, and our interpretation of data is we feel very comfortable around the size, the structure and the timing of the Phase III program given that we've just – given the data that we've just seen.

39. In October 2016, the Company presented more details of the interim endoscopy trial results at the United European Gastroenterology Week conference. On October 17, 2016, the Company summarized this presentation in a press release entitled "Oral GED-0301 Phase 1b Results Show Clinical Remission and Endoscopic Response at Week 12 in Patients with Active Crohn's Disease." The release stated that "Clinical improvement [was] observed early, with highest clinical response and remission rates in the 12-week treatment group." The release also stated that patients

with the most severe endoscopic disease activity had shown the greatest response to treatment, with 63% exhibiting a 25% or greater reduction in their SES-CD score, the study's primary marker of efficacy. Defendant Smith was quoted in the release as stating: "We are encouraged that oral GED-0301 showed both *meaningful endoscopic improvement and clinical remission* at an early time point in this study . . . ." The release continued in pertinent part:

Celgene International Sàrl, a wholly-owned subsidiary of Celgene Corporation (NASDAQ: CELG), today announced that data from a randomized, double-blind, multicenter, exploratory phase 1b study evaluating the effects of investigational oral GED-0301 (mongersen) 160 mg on both endoscopic response and clinical remission in patients with active Crohn's disease will be presented in Vienna, Austria at the United European Gastroenterology Week (UEGW).

Patients with active Crohn's disease [Crohn's disease activity index (CDAI) score 220-450], a total simple endoscopic score for Crohn's disease (SES-CD)  $\geq 7$ , or an ileal disease SES-CD  $\geq 4$ , were randomized to three different active treatment regimens of four, eight or 12 weeks of GED-0301 160 mg daily, followed by an observation period off treatment. Endoscopic and clinical assessments were reported through week 12. A total of 63 patients were enrolled in the study.

*The study was designed to further enhance the understanding of GED-0301 activity in a difficult-to-treat, moderate to severe patient population.* This population was more diverse than prior GED-0301 studies and included patients with endoscopically confirmed mucosal damage at entry and those who had previous surgeries. The study also included both biologic-exposed and biologic-naïve patients, as well as patients with a diagnosis of Ileitis, Ileocolitis or colitis.

*Clinical improvement was seen by week 2, and clinical response (CDAI decrease  $\geq 100$ ) and remission (CDAI  $< 150$ ) rates were highest in the 12-week treatment group at 67 and 48 percent respectively, at week 12. The mean CDAI reduction from baseline at week 12 in the 12-week treatment group was 133 points. Of the patients with evaluable*

*endoscopies at week 12 (n=52), 37 percent had an endoscopic response ( $\geq 25$  percent reduction in SES-CD score from baseline), with no meaningful difference across treatment groups. In addition, of those patients with greater endoscopic disease activity at baseline (SES-CD score of  $> 12$ ; n=16), 63 percent exhibited a reduction  $\geq 25$  percent in SES-CD score and 31 percent had a reduction of  $\geq 50$  percent.*

The rates of adverse events and serious adverse events were low and similar across treatment groups. There were no new safety signals for oral GED-0301 160 mg daily reported in this study.

“A significant number of Crohn’s disease patients don’t reach remission with current therapies or will suffer relapses over time and are in need of new treatment options,” said Brian Feagan, MD, Director of Robarts Clinical Trials at Robarts Research Institute, Western University, London, Ontario, Canada. *“Based on these findings, oral GED-0301 has the potential to provide a new, oral option with a novel mechanism of action designed to act locally.”*

“We are encouraged that oral GED-0301 showed both meaningful endoscopic improvement and clinical remission at an early time point in this study,” said Scott Smith, President, Celgene Inflammation & Immunology. *“The fact that this study included nearly 50 percent biologic-experienced patients further reflects the potential of GED-0301 as a novel approach for patients with Crohn’s disease searching for alternatives.”*

40. On October 18, 2016, Celgene held a conference call to discuss the results. On the call, Celgene again touted the trial data as providing further evidence of GED-0301’s revenue potential and sought to dispel any concerns stemming from the CD-001 study’s design. For example, defendant Smith described the results as “*validating*” the prior results of the phase II study. Celgene’s Head of Global Medical Affairs, Pete Callegari, stated: “When we initially discussed GED-0301, we stated that GED-0301 potentially had a transformational profile but still had some evidence that

needed to be assessed in future trials. . . . *With the interim results from CD-001, we now feel more confident most of the questions have been addressed.*”

41. During the call, one analyst questioned why the Company had failed to include a control placebo arm, asking, “I guess I am wondering just what’s the best defense here that there is a true drug effect as opposed to just a reversion to the mean in a patient population that’s very severe at the baseline?” Defendant Smith responded, as he had earlier, that the lack of a placebo control arm did not take away from the import of the results or the integrity of the trial’s design, stating:

If you take a look at a number of different things, it was a little bit patient poor, but data rich, as we look at things, which was the reason for not having a placebo arm.

When I take a look at this particular study, you see in a relatively heterogeneous, more severe, more difficult to treat population, you see a very positive sign in terms of clinical response and clinical remission, a *very validating* of what we have seen in the IGON program [*i.e.*, the phase II trial]. And then when you take a look at the other markers at week 12, which is an early time point for endoscopic healing and endoscopic response, you see signs of endoscopic improvement in all three treatment groups and you see biomarkers generally going in the right direction.

*So that cumulative evidence really tells you that not only are you having a pretty significant effect from a response and remission standpoint, but you are also seeing everything go in the direction that you would like to see it go.* And then also from an endoscopic perspective, you are seeing sort of the largest responses in the patients with most extensive disease, which I think is a very positive sign of drug activity as well.

42. A doctor involved in the study design presenting on behalf of Celgene, William Sandborn, echoed these justifications for the lack of a control arm, stating

that the endoscopic placebo effect for patients with the baseline severity of those in the study “tends to be nearly zero,” and that, as a result, the trial’s data were “all pretty reassuring.”

43. On October 27, 2016, Celgene issued a press release announcing its financial results for the quarter ended September 30, 2016. The Company reported net product sales of approximately \$2.97 billion. Defendant Alles was quoted in the release as stating: ““Continued outstanding execution by our teams around the world led to another strong quarter of revenue growth and progress advancing many of our most important strategic programs . . . . Our increasing enterprise-wide momentum has us on-track to exceed key 2016 objectives and positions us well for sustained long-term growth.”” The results were included in Celgene’s Form 10-Q filed with the SEC that same day and were certified by defendants Alles and Kellogg as truthful, not misleading and free from fraud.

44. Also on October 27, 2016, Celgene hosted an earnings conference call to discuss the quarterly results. On the call, defendants continued to tout the interim CD-001 trial data and the promise of GED-0301. For example, defendant Alles stated that the recent results “continue to demonstrate this *transformative potential* of . . . GED-301 in Crohn’s disease.” Similarly, defendant Smith stated: “The CD-001 results are generally consistent with the clinical outcome seen in the placebo controlled IGON program,” which provided “compelling evidence to view GED-0301 as a potentially

transformational therapy.” He continued, “Once confirmed in pivotal programs, *we are confident this product will be transformational for patient care.*”

45. In the following months, defendants repeatedly hailed GED-0301 as one of Celgene’s most promising treatments and important assets. For example, during a November 15, 2016 analyst conference, defendant Smith stated in pertinent part:

We see a tremendous opportunity for GED in the marketplace.

\* \* \*

So you get the data and I was very, very pleased with the data. *I mean, it showed that the drug is continuing to work.* You see really high levels of clinical response and clinical remission. And then we saw what we wanted to see from an endoscopic perspective, which is patients seeing improvement in their endoscopic scores and biomarkers moving in the right direction.

\* \* \*

And in this case, we saw something going on.

And the other thing I think that was very interesting is 63% of patients who had extensive disease saw 25% improvements in SES-CD score, which is sort of what you are after and what you’re looking at. The SES-CD is a little harder to read with patients with less severe disease. But when they have extensive disease, that’s when you can get a real handle on whether the drug is working. We saw 63% of patients with 25% improvement.

So we were very, very pleased with that study. I think it showed the drug works in all kinds of different patients.

\* \* \*

So for me, the GED program is just so exciting. It’s such a different type of therapeutic than has been in the market. You see different responses and remission rates than you see with anything else. And then it’s an oral drug, non-systemically absorbed. In the Phase II

program, the side effects look like placebo in that case. *There's a real opportunity for this to really change the whole shape of the market in terms of IBD.*

46. Likewise, defendant Alles stated during a January 9, 2017 analyst conference that GED-0301, together with Otezla and Ozanimod, provided “an opportunity to, literally, *change the entire landscape* of how these diseases are treated over the next year to 10 years” and a “fantastic opportunity for us to create a *multi-billion-dollar add on* to our current product portfolio.” He continued:

We've developed unique partnerships with so many collaborators and scientists that we feel very, very good about our pipeline. Our mission and vision is clear. And when I think about our strategy of adding and accelerating to our core strengths, we are in a great position to continue to grow; not only for 2017 and into 2020, but into the next decade and beyond.

47. On January 26, 2017, Celgene issued a press release announcing its financial results for the quarter and year ended December 31, 2016. The Company reported net product sales of \$2.98 billion for the quarter and \$11.18 billion for the year. The press release also provided guidance for 2017 of \$13.0 billion to \$13.4 billion in total revenues, including \$1.5 billion to \$1.7 billion in net sales for Otezla. Defendant Alles stated: “2016 was an outstanding year of progress strengthening our commercial portfolio and advancing our early-, mid- and late-stage pipeline . . . . We expect our business momentum and significant near-term catalysts to drive high-growth through 2017 and beyond.” The results were later included in Celgene's

Form 10-K filed with the SEC on February 10, 2017 and were certified by defendants Alles and Kellogg as truthful, not misleading and free from fraud.

48. Also on January 26, 2017, Celgene hosted an earnings conference call to discuss the quarterly and annual results. On the call, defendant Smith stated: “This year we expect to fully enroll critical studies in our IBD program, including the large treat-through pivotal trial for GED 301 in the treatment of Crohn’s disease. We are very excited about the transformational potential of this novel oral treatment approach in an area of very high unmet medical need.”

49. On April 27, 2017, Celgene issued a press release announcing its financial results for the quarter ended March 31, 2017. The Company reported net product sales of \$2.95 billion for the quarter. The press release also raised adjusted earnings per share (“EPS”) guidance for 2017, from a range of \$7.10 to \$7.25 to a range of \$7.15 to \$7.30. Defendant Alles stated: ““Our significant first quarter operational, financial and strategic progress strengthen our confidence and outlook for 2017 . . . . Our business momentum is increasing as we continue to generate meaningful catalysts and long-term value drivers.”” The results were included in Celgene’s Form 10-Q filed with the SEC that same day and were certified by defendants Alles and Kellogg as truthful, not misleading and free from fraud.

50. Also on April 27, 2017, Celgene hosted an earnings conference call to discuss the quarterly results. On the call, defendants claimed that subsequent data

from CD-001 had continued to validate GED-0301's efficacy, further confirming that Celgene and its top management had reviewed data and analysis from the trial that was not publicly available. For example, defendant Smith stated that he was "very, very" excited about the "tremendous potential" of GED-0301 following his receipt of more undisclosed interim trial data:

There is a sort of an encore presentation of some of the GED, CD-001 data upcoming, which takes a look at the relationship between clinical remission and endoscopic improvements. And so I can't give specifics to that data, but that will be presented at DDW coming up. *So we're excited about that. We're very, very – we've got data for GED, obviously, and for ozanimod. We're very excited about both assets.* The GED registration program has really accelerated over the last little while. We remain on track with time lines there, and we think *there's tremendous potential*. Before you finalize positioning, you would want to see and make sure that you have the data from both GED and from ozanimod in Crohn's. I think there is some real positives on the mongersen or GED side in terms of the nonsystemic absorption characteristics of the product, which could make it really, I think, a very good product, both to be used early first line, but also to be used in combination or in combinatorial approaches with other agents in the marketplace. Because again, it's got a very unique mechanism and non-systemically absorbs. *So we're very, very excited about both these assets.*

51. On the call, defendant Alles tied the results to Celgene's revenue potential and 2020 guidance, stating: "All that said, *we remain very confident that we're on track to meet or exceed 2020.*"

52. In subsequent months, defendants continued to tout GED-0301's transformative potential and its ability to replace Revlimid revenues. For example, during a May 17, 2017 analyst conference, defendant Kellogg stated:

And as we get the data, for example, for ozanimod, for GED-301, for luspatercept, for idiphenyl, and so on, those different products that are coming through both our collaboration partners and our own pipeline. That will create kind of the – on the curve, *that will create the new growth drivers that, quite frankly, I think will allow us to grow as we go through the next decade quite nicely.* So it's an exciting time. *I think there is a lot of investor interest in that late stage pipeline for that exact reason and it's appropriate. And we're actually very optimistic.* So I think that's exactly strategically what we want to be focused on. We've got the investors watching the right things, which I think is super. And we're looking forward to kind of having the data come through over the next 18 months.

53. Similarly, during a May 31, 2017 analyst conference, defendant Alles stated: “So beginning with GED-0301, our oligonucleotide that is only absorbed in the colon, and *we've had some great Phase II data* for the products.” Alles also claimed that GED-0301, together with Otezla and Ozanimod, would ultimately serve as a “replacement” for Revlimid revenues, stating in pertinent part:

If I just look at the inflammatory bowel disease franchise, and I look at the 3 products, OTEZLA, ozanimod and GED-0301, in a mix of puts and takes on thinking about success there, all of those molecules with the potential to launch before or around 2020, that revenue alone, *that opportunity alone can offset all of not the annual REVLIMID sales,* right, but whatever the peak is. *This is a replacement for it.*

54. On July 27, 2017, Celgene issued a press release announcing its financial results for the quarter ended June 30, 2017. The Company reported net product sales of \$3.26 billion for the quarter, which included \$358 million in Otezla sales, a 49% increase year-over-year. The press release again raised adjusted EPS guidance for 2017, from a range of \$7.15 to \$7.30 to a range of \$7.25 to \$7.35. Defendant Alles

stated: ““We delivered outstanding second quarter results and significantly advanced our high-potential pipeline . . . . Exceptional execution of key strategic initiatives strengthened and expanded our opportunities for long-term growth.”” The results were included in Celgene’s Form 10-Q filed with the SEC that same day and were certified by defendants Alles and Kellogg as truthful, not misleading and free from fraud.

55. Also on July 27, 2017, Celgene hosted an earnings conference call to discuss the quarterly results. On the call, defendants characterized GED-0301, Ozanimod and Otezla as driving the Company’s growth to meet its 2020 guidance and beyond. For example, defendant Alles stated:

Our second quarter results were outstanding and a strong indicator that our constant focus on operating excellence and innovation has us extremely well positioned to *achieve or exceed our full year 2017 financial targets and continues to support our 2020 outlook*. Given the significant momentum of our blockbuster medicines and the expanding leverage of our business model, we are raising our 2017 adjusted earnings per share guidance to a range of \$7.25 to \$7.35, up from our previous target of \$7.15 to \$7.30.

56. On the call, defendant Curran, who had replaced defendant Smith as the head of Celgene’s I&I segment, described GED-0301 as one of the Company’s “*next-generation growth drivers*.” Similarly, defendant Smith stated that Celgene was “*seeing tremendous momentum in our I&I franchise*[,] as we continue to expand the utilization and access of OTEZLA globally,” and “*continued strong execution of our pivotal IBD programs: GED-0301 in Crohn’s disease*.”

57. Defendant Kellogg made similar rosy statements about the ability of Celgene's key products to drive future growth on the call:

A fantastic quarter. We delivered outstanding results in the second quarter and have great momentum to finish up the year in great shape. But even more important for all of us in the room here, while we continue to drive great top line growth, great bottom line growth and P&L leverage, we are also significantly advancing our [pipeline] and executing on key strategic initiatives that ***really set up the platform for long-term growth through 2020 and into the whole next decade***. And I think you can see a lot of the questions we had today, quite frankly, are about ***the assets that are going to drive us past 2020 and really create a tremendous growth story for us***, and that's what we're all working hard on.

58. Following the call, defendants repeatedly claimed during multiple investor meetings and analyst conferences that GED-0301 would be a multi-billion-dollar replacement for Revlimid, that the Company would meet its 2020 guidance, and that positive sales trends for Otezla had continued from prior quarters. For example, during an August 9, 2017 conference call, defendant Kellogg stated that Celgene was ***"right on track so far"*** with its 2020 guidance.

59. Similarly, during a September 13, 2017 investor conference, defendant Alles continued to hold up GED-0301, Otezla and Ozanimod as key replacements for Revlimid and drivers of future Company sales, stating in pertinent part:

We've turned that ability to generate innovative molecules into a broader, diversified portfolio with 8 therapies approved, OTEZLA, for example, in psoriatic arthritis, increasingly a pipeline of inflammatory bowel disease drugs like GED-0301, ozanimod, et cetera.

. . . [O]ver the next decade and beyond, we're positioned to continue to have high growth.

\* \* \*

So this company now is positioned with the kind of optionality opportunity for growth that's sustained ***not only to our outlook to 2020 where we remain very confident, but beyond the loss of exclusivity of our flagship product, REVLIMID.***

60. During an analyst call the next day, defendant Kellogg made an even more in-depth pitch touting the Company's pipeline products, including GED-0301 and Ozanimod, and the purported continued momentum of Otezla sales throughout the quarter, stating, in pertinent part, that the Company just wanted to be "as transparent as we can with investors" and that

we've been building up a tremendously powerful and rich pipeline, and that is really an important criteria for Celgene's future, is to have a strong pipeline as we go into the next decade. And we feel very strongly about that, and I'll highlight some of the dimensions of that in just a minute.

\* \* \*

[A]s we go from today to 2020, where we've given guidance to have our revenue above \$21 billion, ***we're going to be primarily driven by the main core commercial assets that we have and some of the early emergence of our pipeline assets like ozanimod, GED-0301, et cetera.*** And they're just beginning to ramp up, and that will constitute kind of the vision through 2020. . . . But ***these will be the assets that will drive our business*** through those events and create kind of a nice growth profile for Celgene throughout the entire next decade.

. . . But ***ozanimod, GED-0301, JCAR017, very interestingly, the anti-CD19 program and so on, right? You see here some very, very high potential programs.*** . . .

So overall, listen, we have great momentum with our key commercial assets that are already in place and are driving. We've given guidance to 2020. ***We feel very good about that guidance and continue to execute well on those programs.*** We have a number of pipeline catalysts that create a sense of inflection opportunity for us that will be clearly visible in the next 18 months probably at this point.

\* \* \*

[T]he commercial assets that were included in that 2020 guidance ***are on track*** doing really well. I think everybody would agree with that. The story of Rev, Pom, ABRAXANE, ***OTEZLA***, that really played out beautifully. . . . Obviously, the commercial assets we have are ***doing very well***.

61. Defendant Kellogg also reiterated his confidence that the Company would meet its 2020 guidance and that it was laying the groundwork for its “growth story for the next decade,” stating in pertinent part:

I think giving guidance out to 2020, when we did it, I will admit it was pretty long term. And certainly, have set a new standard for long-term guidance. But the reason we're able to do that is because so much of our commercial profile and our revenue profile was being dictated by the assets that are already on the market, already approved the indications that were there. And we were just helping investors understand that, that was something that we had a fair level of confidence in. I think that when you go beyond 2020, where you want to enhance it, really it's more dependent on the pipeline results. And so I think this makes a lot of sense. ***We like to be as transparent as we can with investors.*** It helps them understand kind of the thought of how to value Celgene. And also what it does is it kind of solves kind of the first time horizon in terms of this is what you should expect from the company in terms of the financial performance; and gets a lot of investors thinking about the next time horizon, kind of ***past 2020, where, in fact, these pipeline of assets that I showed you in my presentation today start to all come through and you can start to think about how they might build the growth story for the next decade.*** I think that is where our valuation is really hinging right now. People do appreciate Rev, Pom and those drugs. But when I think about my 2020 PE or what the valuation is looking beyond 2020, I

think that's where there's still a lot of opportunity for growth and the company's value.

62. As late as September 26, 2017, with only four days left in the third quarter, defendants continued to represent that the GED-0301 trials were showing tremendous promise, that Otezla continued to perform above expectations, and that management was confident it would meet or exceed its 2020 guidance. On that date, defendant Ahmed spoke at an analyst investor conference on all three topics. During his presentation, Ahmed claimed that Celgene and its management now had even greater "visibility" into the revenue potential of GED-0301 and Ozanimod and the current sales for Otezla, among other ongoing trends in the business, which made them "very, very confident about 2020 in terms of meeting or exceeding our expectations." He stated the following in pertinent part:

I did want to start with our mission statement, though. And I think for me, this is a story of both constancy and dynamism. So in terms of being constant, so we continue our intense focus on delivering, researching and commercializing products against the highest unmet needs. And it needs to be dynamic because we're a company that really continues to follow the science wherever that may take us.

\* \* \*

I'd also like to say that the story today is going to be about momentum and inflection. When I refer to momentum, that's the momentum currently of our in-line brands as we think about 2020, and inflection because now *we have greater insight into our pipeline*, we can now start to think about 2020 and beyond.

\* \* \*

*So if you think about 2014, GED; 2015, receptors; EngMab last year, so we're able to make all of these acquisitions but still grow our top line and manage our bottom line extremely, extremely well. And really, it's our current in-line brand momentum and **our visibility to the pipeline that helps us feel very, very confident about 2020 in terms of meeting or exceeding our expectations.***

Over the next 2 years, we're going to see key inflection points for the growth of Celgene in the future. We have made a Phase III data, data readouts over the next 2 years. And also, ***the pipeline visibility now gives us some idea of what pipeline products we think will land in that 2020 time frame*** and then what are the blockbuster potential products for the future as we think of loss of exclusivity for our major brands. So next 2 years are pivotal for Celgene both in terms of our brand momentum and also the emergence of our pipeline.

We feel that we have a very deep and rich pipeline across all stages of development. And really, our strategy focuses on where are the places that we can win, how can we build category-leading franchises with category-leading brands? And if you look at all of these disease segments, ranging from myeloma to solid tumors to I&I, you can see we're on this journey where we're building franchises around key products in the marketplace.

The other thing I'd say also is now that ***we are starting to get greater visibility into our pipeline***, as we think about that time period between 2020 and 2030, we've got multiple products landing both on the early side of that in terms of 2020 but also blockbuster products that take us from 2020 to 2030 as we think about the LOE of our current in-line brands.

\* \* \*

I'm now going to turn our focus to our newest and just as exciting franchise in I&I. We believe – again, using the anchor molecule of ***OTEZLA, where we've seen great success***, we believe we have another opportunity to transform many diseases in this space with our suite of products.

Going back to OTEZLA. I think the thing that has been done very well here is that we've offered a unique value proposition with this brand

to carve out a very unique space in this market, i.e., the prebiological space. And as we think about *our metrics around launch for OTEZLA, the momentum is going very, very well*. Now we have access secured in Europe and Japan. *And so our ex U.S. sales are growing at a greater than 100% clip. So we're very, very happy with where OTEZLA is in the marketplace.*

\* \* \*

And I'll say again, we feel very, very good about our pipeline across franchises. *And now that we have visibility to the emerging data, we feel good about the contribution to 2020 from our pipeline*, but even more importantly, about the contribution of our pipeline from 2020 into the next decade.

I spoke about the pivotal inflection points. And so again, that sweet spot of going beyond 2020, our pipeline is rapidly emerging. Even as we think about 2020, we will have 15 brands approved on the market, which doubles the commercial portfolio that we have today.

And as you think about the individual molecules, we have, in the next few years, 12 molecules that can be approved, we've already checked off IDHIFA, 10 of those with \$1 billion-plus potential, 4 of those with a multibillion dollar-plus potential. So we're feeling very, very good about the promise of our pipeline.

And lastly, to close out this discussion, we started talking about momentum. So again, *reaffirming our 2020 guidance, I'm feeling very, very good and confident about the momentum that we have* with our in-line brands as we think about 2020.

We spoke about inflection. And I think now, with the insight into our emerging pipeline, we feel very good about inflection that our pipeline offers to both 2020 and beyond. And I think – we started with our mission statement. We will continue relentless and bold pursuits in the area of science, including acquisitions, business development activities. And I think by doing this, we feel very, very good about the strength and the position that Celgene occupies in the marketplace not just today, not just 2020, but into the next decade, from 2020 to 2030 and beyond.

63. The statements referenced in ¶¶36 and 38-62 above were materially false and/or misleading when made because they misrepresented and/or failed to disclose the following adverse facts pertaining to the Company's business, operations and financial condition, which were known to defendants or recklessly disregarded by them. Specifically, defendants failed to disclose:

(a) that the CD-001 interim endoscopy trial suffered from fatal design defects, including, *inter alia*, insufficient patient size and lack of a placebo control arm, that prevented the trial from providing meaningful data regarding the efficacy for GED-0301 or for informing the proper design of the ongoing CD-002 phase III trial;

(b) that GED-0301 had failed to demonstrate meaningful clinical efficacy through the interim endoscopy trial because of the trial's design defects and because the primary marker of efficacy used in CD-001 – 25% endoscopic improvement from baseline – was insufficient to indicate clinically meaningful improvement when accounting for placebo effects;

(c) that non-public interim trial data received and analyzed by Celgene and its representatives demonstrated GED-0301's lack of efficacy and a revision to baseline in the treated patient population;

(d) that, as a result of (a)-(c), there was an undisclosed risk and high likelihood that Celgene would be unable to develop GED-0301 into a commercially viable treatment for Crohn's disease;

(e) that the growth of Otezla sales had dramatically slowed during Celgene's third fiscal quarter of 2017, from 41% annual growth for U.S. sales in the second quarter of 2017 to only 2% annual growth during the third quarter;

(f) that international sales for Otezla had grown only 87% year-over-year during the third quarter of 2017, far below the "greater than 100% clip" represented to investors, and such adverse sales trends were worsening;

(g) that, as a result of (a)-(f) above, the Company was not on track to achieve its 2017 or 2020 fiscal guidance, and such guidance lacked a reasonable basis.

64. On October 19, 2017, the Company issued a press release entitled "Celgene Provides Update on GED-0301 (mongersen) Inflammatory Bowel Disease Program." The release stated that Celgene would be discontinuing the GED-0301 trials for the treatment of Crohn's disease following a futility analysis by an independent Data Monitoring Committee. A report on Form 8-K filed that same day stated that Celgene expected to record a \$1.6 billion impairment charge (with certain offsets) as a result of the drug's failure.

65. The news stunned investors, who had long been led by defendants to believe that GED-0301's interim data had demonstrated the drug's efficacy. On this news, the price of Celgene stock fell \$14.63 per share to close at \$121.33 per share on October 20, 2017, a one-day decline of nearly 11%, on abnormally heavy trading volume.

66. Approximately one week later, on October 26, 2017, the Company issued a press release announcing its third quarter 2017 financial results. The results missed expectations, with total net product sales of only \$3.28 billion, representing less than 1% growth from the prior quarter. Most shocking, the Company revealed that Otezla sales had actually ***declined*** compared to the second quarter, from \$358 million to \$308 million, a drop of nearly 14%. The slowdown in Otezla's U.S. sales growth was particularly striking, as it had slowed to only 2% annual growth in the third quarter, compared to a 41% annual growth rate in the second quarter. Similarly, the Company's international sales had fallen to only 87% growth year-over-year.

67. The Company also slashed its 2017 and 2020 fiscal guidance, which defendants had repeatedly reaffirmed, including as recently as one month before – at a time when they ***already had*** almost the entirety of Celgene's third quarter results. Total sales from Otezla were now projected to be only \$1.25 billion for 2017, a greater than ***21% reduction*** from the mid-point of the prior guidance range. Worse still, Celgene revised downward its 2020 guidance as a result of the poor results and the loss of projected GED-0301 revenues. While guidance for total product sales was lowered from \$21 billion to a range of \$19 billion to \$20 billion, management ***raised*** projections for Revlimid and its existing hematology products, with these drugs' proportion of overall sales increasing from 62% in the original guidance to up to 77% of total projected product sales in the revised guidance. Consequently, the Company

revealed that it was much more dependent on Revlimid sales for its future success than previously disclosed. Total I&I sales (which included GED-0301 and Otezla) were now projected to be between \$2.6 billion to \$2.8 billion, when they had previously been slated to exceed \$4 billion.

68. On this news, the price of Celgene stock plummeted \$19.57 per share to close at \$99.99 per share on October 26, 2017, a one-day decline of over 16%, on abnormally high trading volume.

69. The market's reaction was swift and severe, resulting in the loss of billions of dollars in market capitalization in the span of a week. Several analysts downgraded the stock, with market commentators characterizing the results as “*disastrous*” and “*truly catastrophic*.” One J.P.Morgan analyst noted that “management faces a major credibility issue.” Likewise, a Cowen analyst wrote that investors were “likely to be very concerned,” as they had relied on management to “provide an accurate description” of Otezla sales and the reported shortfall “is likely to impact the company’s credibility.” According to investor news service *SeekingAlpha*, Celgene’s third quarter results had “shocked investors,” as “the Street has suddenly lost trust in Celgene’s pipeline as well as the credibility of management’s guidance.”

70. Despite the stock price declines as a result of these adverse disclosures, the price of Celgene stock remained artificially inflated as defendants continued to

misrepresent and/or conceal material information from investors. Specifically, defendants sought to reassure investors by claiming that the approval of Celgene's third purported revenue driver in its I&I segment, Ozanimod, would offset the lost GED-0301 opportunity and declining Otezla sales and serve as a replacement for Revlimid revenues. However, defendants failed to disclose that Celgene had not collected sufficient nonclinical and clinical pharmacology data for Ozanimod in recent clinical trials to allow for FDA review. Instead, defendants continued to represent that the NDA for Ozanimod would be sent to the FDA by the end of the year, despite this lack of data, in order to allay investor concerns over the Company's operational setbacks.

71. For example, on October 26, 2017, during the same conference call in which defendants revealed Celgene's disappointing third quarter financial results, defendants pointed to the potential of Ozanimod. In his prepared remarks, defendant Alles stated in pertinent part:

While sales of GED-0301 were relatively modest in our 2020 model, we did forecast multibillion dollar peak sales potential. We are encouraged by the recently presented ozanimod Phase II data in Crohn's disease and expect to initiate a Phase III study of this novel agent in Crohn's within the next few months. We are committed to building a leading inflammatory bowel disease franchise, *now led by ozanimod*, for the treatment of ulcerative colitis and Crohn's and perhaps OTEZLA in one or both of these serious unmet medical conditions. *And this immediate shift from GED-0301 to ozanimod in Crohn's disease is a great example of the pipeline optionality and opportunity we have built and continue to build into our research model for hematology, oncology and inflammation and immunology.*

72. During the same call, defendant Curran stated that Celgene had continued to make “good progress” in developing Ozanimod and that the drug “***remains on track for regulatory submission***, beginning with the U.S. by year-end and the EMEA in the first half of 2019.”

73. Two days later, on October 28, 2017, defendants held a conference call with investors focused on Ozanimod and recent trial results that would underpin the Company’s submission to the FDA. On the call, defendant Curran stated that Ozanimod could become a key driver in several areas and a “best-in-class” treatment option for patients. Curran stated in pertinent part:

So before we get into the presentations, it’s really exciting to be finally here in Paris and able to share the Phase III data. But important to say that ozanimod doesn’t just have a future in MS, but ***will become a potential key driver for the I&I franchise in both neuroscience and gastroenterology and dermatology and rheumatology***.

If you look at the neuroscience segment of the market, ***it really will be a cornerstone product in RMS and has the potential to be the best-in-class oral***. As you saw over the last couple of days, we’ve demonstrated superiority versus Avonex across multiple key endpoints in both the trials, and we believe we have a differentiated risk benefit profile, which we’ll talk a little bit more about through the – about during the presentation.

74. Defendants also highlighted the quality of the data that Celgene would be submitting to the FDA as part of the NDA for Ozanimod. For example, Company representatives Jeffrey Cohen and Philippe Martin stated, respectively, that the data was obtained through “***very rigorously performed trials***,” which would “form the

basis of [Celgene's] submission to the FDA and to EMA.” Defendant Curran, after highlighting the “market opportunities” for Ozanimod, again stated that the Company was on track “to fil[e] or submit[ a] filing by the end of the year in the U.S. and the EMEA the first half of next year.” When asked by an analyst whether the Company had “enough data” on Ozanimod for a favorable label determination from the FDA, Company representative Philippe Martin responded that the “*data we have is particularly compelling in our minds.*” Similarly, defendant Smith stated that the data Celgene had collected for Ozanimod was the “*best case scenario for being able to make a really positive, strong argument [to the FDA] and certainly we will.*”

75. On November 7, 2017, Celgene hosted another conference call with investors, during which defendant Kellogg touted the “very promising” and “detailed data for ozanimod in multiple sclerosis.” Kellogg described Ozanimod as a “*high-potential asset*[],” and stated that he was “relatively *bullish* on the opportunity for multiple sclerosis.”

76. Defendants increased their rhetoric promoting Ozanimod after Celgene submitted the NDA for the drug to the FDA at the end of 2017. On a January 8, 2018 conference call, defendant Alles called Ozanimod the “*platform molecule* for the company,” a “*multibillion-dollar blockbuster*,” and a “*derisked asset*” because of its multiple potential applications. In his prepared remarks, Alles once again highlighted

the quality of the data the Company had submitted to the FDA in seeking the drug's approval:

And of course, in neurosciences, we're very proud and pleased with the results of the 2 Phase III trials that were released last year and presented at ECTRIMS late in the year. We believe that the efficacy from these 2 trials comparing ozanimod to Avonex in relapsing-remitting MS ***presents a highly favorable and competitive position for the brand, starting with the efficacy and then moving through the favorable safety and tolerability profile.*** We are very excited about it. ***As I said, the NDA was submitted the end of last year. We look forward to working with the FDA to bring this molecule to patients in the U.S. and then around the world as quickly as possible.***

77. Similarly, during this same call, defendant Curran called Ozanimod a ***"foundational compound*** in neurology." Defendant Smith, meanwhile, stated that the drug had the potential to meet ***"tremendous unmet medical need now."***

78. During a January 25, 2018 conference call, defendant Curran stated that the data submitted to the FDA ***"support a differentiated clinical profile"*** and that the Company was "preparing for a world-class launch in the RMS market" for Ozanimod. She continued, ***"With ozanimod, we are planning to secure FDA approval in RMS by year-end"*** and to submit international registration dossiers in 2018 starting with Europe in Q1." Later, in response to an analyst question about potential monitoring requirements for Ozanimod, Curran stated: ***"Clearly, from the data, we have a highly differentiated compound both in terms of efficacy, safety and tolerability.*** So we'll continue to discuss the potential label with the authorities but at this case – at this stage that is the base case."

79. Defendant Smith likewise pointed to the Company's "**execution**" on Ozanimod and the fact that it had submitted "***the NDA for ozanimod and RMS . . . on the heels of 2 positive global Phase III studies.***" He also stated that Celgene was "currently building out a strong neuroinflammation team to execute a launch and ***unlock the value of this important product.***" Smith, likewise, represented that Ozanimod together with the Company's other pipeline products "***could yield over \$16 billion in incremental peak revenue*** through 2030."

80. On February 7, 2018, Celgene filed its financial results on Form 10-K for the quarter and year ended December 31, 2017. The Form 10-K described Ozanimod as "***a potential best-in-class SIP receptor modulator***" and stated that the Company had submitted an NDA for Ozanimod to the FDA in December 2017 "based on data from the phase III trials evaluating ozanimod in patients with RMS." The Form 10-K was signed by defendants Alles and Kellogg, who certified that the filing was truthful, not misleading and was free from fraud.

81. Then, on February 27, 2018, after the market closed, Celgene issued a press release revealing that the FDA had sent a Refusal to File letter for the Company's NDA for Ozanimod. The release stated that ***both*** the clinical and nonclinical pharmacology data were insufficient to even permit a complete review by the FDA:

Upon its preliminary review, the FDA determined that the nonclinical and clinical pharmacology sections in the NDA were

insufficient to permit a complete review. Celgene intends to seek immediate guidance, including requesting a Type A meeting with the FDA, to ascertain what additional information will be required to resubmit the NDA.

82. On this news, the price of Celgene stock fell \$8.66 per share to close at \$87.12 per share on February 28, 2018, a one-day decline of over 9%, on abnormally high trading volume.

83. Market commentators panned the announcement. An analyst at *SeekingAlpha* called the news “hard to accept as a reality,” because receiving a Refusal to File letter is “*almost unheard of for a major company.*” Likewise, an analyst at Leerink stated that “*Celgene could have seen this coming*” and ““*clearly made a decision to file this application at risk*, despite late information that might have been more thoroughly disclosed and explored in the application, had the filing been postponed by a few months.””

84. As a result of these disclosures, the price of Celgene stock dropped more than 40% from its Class Period high, causing economic loss and damages under the federal securities laws to plaintiff and the Class.

### **LOSS CAUSATION AND ECONOMIC LOSS**

85. During the Class Period, as detailed herein, defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Celgene common stock and operated as a fraud or deceit on purchasers of Celgene common stock. As detailed above, when the truth about Celgene’s

misconduct was revealed, the value of the Company's stock declined precipitously as the prior artificial inflation no longer propped up the stock's price. The declines in Celgene's stock price were the direct result of the nature and extent of defendants' fraud finally being revealed to investors and the market. The timing and magnitude of the share price declines negate any inference that the loss suffered by plaintiff and other members of the Class was caused by changed market conditions, macroeconomic or industry factors or Company specific facts unrelated to the defendants' fraudulent conduct. The economic loss, *i.e.*, damages, suffered by plaintiff and other Class members, was a direct result of defendants' fraudulent scheme to artificially inflate the price of the Company's stock and the subsequent significant decline in the value of the Company's stock when defendants' prior misrepresentations and other fraudulent conduct were revealed.

86. At all relevant times, defendants' materially false and misleading statements or omissions alleged herein directly or proximately caused the damages suffered by the plaintiff and other Class members. Those statements were materially false and misleading through their failure to disclose a true and accurate picture of Celgene's business, operations and financial condition, as alleged herein. Throughout the Class Period, defendants issued materially false and misleading statements and omitted material facts necessary to make defendants' statements not false or misleading, causing the price of Celgene stock to be artificially inflated. Plaintiff and

other Class members purchased Celgene stock at those artificially inflated prices, causing them to suffer damages as complained of herein.

### **APPLICABILITY OF PRESUMPTION OF RELIANCE**

87. At all relevant times, the market for Celgene common stock was an efficient market for the following reasons, among others:

(a) Celgene stock met the requirements for listing and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) according to the Company's Form 10-K filed February 7, 2018, the Company had approximately 752 million shares outstanding as of February 2, 2018, demonstrating a very active and broad market for Celgene common stock;

(c) Celgene was qualified to and did file a less comprehensive Form S-3 registration statement with the SEC that is reserved, by definition, to well-established and largely capitalized issuers for whom less scrutiny is required;

(d) as a regulated issuer, Celgene filed periodic public reports with the SEC;

(e) Celgene regularly communicated with public investors via established market communication mechanisms, including the regular dissemination of press releases on national circuits of major newswire services, the Internet and other wide-ranging public disclosures; and

(f) unexpected material news about Celgene was rapidly reflected in and incorporated into the Company's stock price during the Class Period.

88. As a result of the foregoing, the market for Celgene common stock promptly digested current information regarding Celgene from publicly available sources and reflected such information in Celgene's stock price. Under these circumstances, all purchasers of Celgene common stock during the Class Period suffered similar injury through their purchases of Celgene common stock at artificially inflated prices, and a presumption of reliance applies.

#### **NO SAFE HARBOR**

89. Defendants' false or misleading statements during the Class Period were not forward-looking statements ("FLS"), or were not identified as such by defendants, and thus did not fall within any "Safe Harbor."

90. Celgene's verbal "Safe Harbor" warnings accompanying its oral FLS issued during the Class Period were ineffective to shield those statements from liability.

91. Defendants are also liable for any false or misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer of Celgene who knew that the FLS was false. Further, none of the historic or present tense statements made by defendants were assumptions underlying or relating to any

plan, projection or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made.

### **CLASS ACTION ALLEGATIONS**

92. Plaintiff brings this action on behalf of all persons or entities who purchased Celgene common stock during the Class Period and were damaged thereby (the “Class”). Excluded from the Class are the defendants and their immediate families, the officers and directors of the Company and their immediate families, their legal representatives, heirs, successors or assigns, and any entity in which any of the defendants have or had a controlling interest.

93. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Celgene common stock was actively traded on the NASDAQ. While the exact number of Class members is unknown to plaintiff at this time and can only be ascertained through appropriate discovery, plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Celgene or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions. These shares are held by hundreds or thousands of individuals

located geographically throughout the country. Joinder would be highly impracticable.

94. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of the federal laws complained of herein.

95. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

96. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by defendants' acts as alleged herein;

(b) whether defendants acted knowingly or recklessly in issuing false and misleading statements;

(c) whether the price of Celgene common stock during the Class Period was artificially inflated because of defendants' conduct complained of herein; and

(d) whether the members of the Class have sustained damages and, if so, the proper measure of damages.

97. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

## **COUNT I**

### **For Violation of §10(b) of the 1934 Act and Rule 10b-5 Against All Defendants**

98. Plaintiff incorporates the foregoing paragraphs by reference.

99. During the Class Period, defendants disseminated or approved the false or misleading statements specified above, which they knew or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

100. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

(a) Employed devices, schemes and artifices to defraud;

(b) Made untrue statements of material fact or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) Engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Celgene common stock during the Class Period.

101. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Celgene common stock. Plaintiff and the Class would not have purchased Celgene common stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

102. As a direct and proximate result of defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of Celgene common stock during the Class Period.

## **COUNT II**

### **For Violation of §20(a) of the 1934 Act Against All Defendants**

103. Plaintiff incorporates the foregoing paragraphs by reference.

104. During the Class Period, defendants acted as controlling persons of Celgene within the meaning of §20(a) of the 1934 Act. By virtue of their positions and their power to control public statements about Celgene, the Individual Defendants

had the power and ability to control the actions of Celgene and its employees. Celgene controlled the Individual Defendants and its other officers and employees. By reason of such conduct, defendants are liable pursuant to §20(a) of the 1934 Act.

### **PRAYER FOR RELIEF**

WHEREFORE, plaintiff prays for judgment as follows:

- A. Determining that this action is a proper class action, designating plaintiff as Lead Plaintiff and certifying plaintiff as class representative under Rule 23 of the Federal Rules of Civil Procedure and plaintiff's counsel as Lead Counsel;
- B. Awarding plaintiff and the members of the Class damages and interest;
- C. Awarding plaintiff's reasonable costs, including attorneys' fees; and
- D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

## **JURY DEMAND**

Plaintiff demands a trial by jury.

DATED: March 29, 2018

CARELLA, BYRNE, CECCHI, OLSTEIN,  
BRODY & AGNELLO, P.C.

/s/ James E. Cecchi

---

JAMES E. CECCHI

5 Becker Farm Road  
Roseland, NJ 07068  
Telephone: 973/994-1700  
973/994-1744 (fax)  
jcecchi@carellabyrne.com

ROBBINS GELLER RUDMAN  
& DOWD LLP  
SAMUEL H. RUDMAN  
58 South Service Road, Suite 200  
Melville, NY 11747  
Telephone: 631/367-7100  
631/367-1173 (fax)

ROBBINS GELLER RUDMAN  
& DOWD LLP  
DAVID C. WALTON  
BRIAN E. COCHRAN  
655 West Broadway, Suite 1900  
San Diego, CA 92101  
Telephone: 619/231-1058  
619/231-7423 (fax)

VANOVERBEKE, MICHAUD &  
TIMMONY, P.C.

MICHAEL J. VANOVERBEKE

THOMAS C. MICHAUD

79 Alfred Street

Detroit, MI 48201

Telephone: 313/578-1200

313/578-1201 (fax)

Attorneys for Plaintiff